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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,652	03/14/2007	Orhun K. Muratoglu	00952-8143	4388

90628 7590 04/13/2012

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EXAMINER	
PEPITONE, MICHAEL F	

ART UNIT	PAPER NUMBER
1767	

NOTIFICATION DATE	DELIVERY MODE
04/13/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	**Application No.** 10/597,652	**Applicant(s)** MURATOGLU ET AL.	
	Examiner MICHAEL PEPITONE	**Art Unit** 1767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *125-186* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *125-186* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/18/11*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/24/10 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 125-127, 129-134, 136, 138-140, 142-146, 148, and 151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US 6,448,315).

Regarding claims 125, 127, 129-131, 136, 138-139, 146, 148, and 151: Lidgren *et al.* teaches ultra-high molecular weight polyethylene (UHMWPE powder) particles doped with an antioxidant {doped with vitamin E (α-tocopherol)} (abstract, 1:5-11; 3:63-4:3; 4:15-32; 4:45-50; 8:33-34; ex. 1-2) via mixing UHMWPE with Vitamin E and then diffusion doping {supercritical CO_2} (4:46-5:11); with subsequent exposure to γ-irradiation at a dose above 2 Mrad, followed by annealing at a temperature of above 80 °C {remelting} (6:8-18; 6:45-68; 7:1-15); wherein irradiating/annealing can be carried out at any stage in the manufacturing process, from powder to implant (6:16-18). Lidgren *et al.* teaches medical implants (6:1-7). Lidgren *et al.* teaches compression molding the UHMWPE particles doped with vitamin E into blocks {consolidation}, and machining rods from the blocks {deforming}, with subsequent exposure to γ-irradiation (7:1-15).

Lidgren *et al.* does not teach the process steps in the same order of instant claim 125. However, a prima facie case of obviousness exists where changes in the sequence of adding ingredients derived from the prior art process steps. *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.) [See MPEP 2144.04].

Lidgren *et al.* does not teach γ-irradiating at a temperature above room temperature {RT}. However, a prima facie case of obviousness exists where the claimed ranges and prior art

ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) [See MPEP 2144.05]. Therefore, at the time of invention a person of ordinary skill in the art would have found it obvious to have irradiated at a temperature above room temperature as above room temperature is close enough to room temperature.

Regarding claims 126: Lidgren *et al.* teaches implants produced by mechanical processing {turning, machining} (6:1-10; 7:1-15).

Regarding claims 132-134, 140: Lidgren *et al.* teaches γ-irradiation at a dose above 2 Mrad, as well as between 0–200 kGy, with specific doses of 80, 100 and 200 kGy at room temperature (6:8-18; 6:45-68; 7:1-15; Table 1).

Regarding claim 139: Lidgren *et al.* teaches the basic claimed method [as set forth above with respect to claim 125].

Lidgren *et al.* does not teach machining an implant, then doping the implant, followed by annealing the implant. However, a prima facie case of obviousness exists where changes in the sequence of adding ingredients derived from the prior art process steps. *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.) [See MPEP 2144.04].

Regarding claims 142-144: Lidgren *et al.* teaches 0.005-5 wt% vitamin E (α-tocopherol) (5:61-65); with a specific embodiment employing 0.5 wt% (6:36-41; 7:1-36; Table 1).

Regarding claim 145: Lidgren *et al.* teaches the basic claimed method [as set forth above with respect to claim 125]; wherein a variety of antioxidants can be employed, including α- and δ-tocopherol, vitamin E (4:15-32).

Lidgren *et al.* does not teach an example comprising more than one antioxidant, However, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) [see MPEP 2144.06].

Regarding claim 147: Lidgren *et al.* teaches joint prostheses (6:1).

Claims 135 and 137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US 6,448,315), as applied to claim 125 above, in further view of Saum *et al.* (US 2002/0107300), when taken with Wolf *et al. J. Mat. Sci.: Mat in Med*, **2006**, *17*, 1341-1347.

Regarding claims 135: Lidgren *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 125].

Lidgren *et al.* does not teach electron beam irradiation [instant claim 135]. However, Saum *et al.* teaches a method of making crystalline crosslinked ultrahigh molecular weight polyethylene (UHMWPE) implants (abstract, ¶ 9, 13); wherein the implant irradiated with γ-irradiation or electron beam radiation (¶ 13). Lidgren *et al.* and Saum *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of irradiated UHMWPE for medical implants. At the time of invention a person of ordinary skill in

the art would have found it obvious to have combined electron beam radiation, as taught by Saum *et al.* in the invention of Lidgren *et al.*, and would have been motivated to do so since Saum *et al.* suggests that γ-irradiation and electron beam radiation are equivalent forms of radiation (¶ 13).

Wolf *et al.* provides evidence that α-tocopherol fails to show any in-vitro cytotoxic or genotoxic activity when used in-vitro in UHMWPE implants (abstract).

<u>Regarding claims 137:</u> Lidgren *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 125]; wherein the implant is packaged and sterilized (6:1-8).

Lidgren *et al.* does not teach sterilization via ionizing gas radiation or gas sterilization [instant claim 137]. However, Saum *et al.* teaches a method of making crystalline crosslinked ultrahigh molecular weight polyethylene (UHMWPE) implants (abstract, ¶ 9, 13); wherein the implant is packaged and gas plasma sterilized (¶ 20). Lidgren *et al.* and Saum *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of irradiated UHMWPE for medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined gas plasma sterilization of the packaged implant, as taught by Saum *et al.* in the invention of Lidgren *et al.*, and would have been motivated to do so since Saum *et al.* suggests that gas plasma sterilization of packaged implants is known in the art (¶ 20).

Claim 141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US 6,448,315), as applied to claim 125 above, and further in view of Mckellop *et al.* (WO 99/52474).

Regarding claim 141: Lidgren *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 125].

Lidgren *et al.* does not teach irradiating at a temperature of above the melting point of UHMWPE [instant claim 141] However, Mckellop *et al.* teaches UHMPE for medical implants (pg. 1, ln. 25-30; pg. 3, ln. 10-21) irradiated at a temperature above the melt [instant claims 141] (pg. 20, ln. 1-2) {note $T_{m\,peak}$ of UHMWPE ~135 °C}. Lidgren *et al.* and Mckellop *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of irradiated UHMWPE for medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined irradiating at a temperature above the melt (pg. 20, ln. 1-2), as taught by Mckellop *et al.* in the invention of Lidgren *et al.*, and would have been motivated to do so since Mckellop *et al.* suggests that irradiated at a temperature above the melt provides a desired maximum crosslinking in the surface layer and a ate of decrease below his layer, in order to get the required improvement in wear resistance in a surface layer of desired thickness (pg. 20, ln. 1-15).

Claim 149-152 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US 6,448,315), as applied to claim 125 above, in further view of Muratoglu *et al.* (US 2003/0149125).

Regarding claims 149-152: Lidgren *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 125].

Lidgren *et al.* does not teach mechanical deformation uniaxially [instant claim 149], or deformation at a compression ratio of about 2.5 at a temperature of about 130 °C [instant claim

150]. However, Muratoglu *et al.* teaches UHMPE for medical implants (¶ 1, 9), wherein the irradiated UHMWPE undergoes uniaxial deformation (¶ 27), specifically uniaxial compression deformation at about 133 °C with a compression ratio of about 2, or about 4.5 (¶ 90, 97, 112, 116). Lidgren *et al.* and Muratoglu *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of irradiated UHMWPE for medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined uniaxial compression deformation at about 133 °C with a compression ratio of about 2, as taught by Muratoglu *et al.* in the invention of Lidgren *et al.*, and would have been motivated to do so since Muratoglu *et al.* suggests that mechanical deformation at an elevated temperature reduces the concentration of residual free radicals (¶ 48, 99, 119-120).

Claims 128 and 153-154 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US 6,448,315), as applied to claim 125 above, in further view of Burstein *et al.* (US 6,620,198).

Regarding claims 128 and 153-154: Lidgren *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 125]; wherein implants, especially joint prostheses, are fabricated from the UHMWPE having excellent wear resistance via compression molding directly into implants or into blocks from which the implant is machined (6:1-18).

Lidgren *et al.* does not specifically teach forming an interface or an interlocked hybrid material. However, Burstein *et al.* teaches composite bearing inserts for knee joints (abstract), wherein the tibial component includes a metal tibial element and a composite bearing insert structure attached to the metal tibial element. The polymeric bearing is interlocked with the

metal tibial element [instant claims 128, 154] (1:65-2:7; 2:16-25), wherein the polymeric material includes UHMWPE (5:1-7), and the polymer insert and tibial tray are interlocked through dovetails, or screw arrangement {porous (metallic) material} [instant claim 153] (2:10-25). Lidgren *et al.* and Burstein *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of medical implants containing UHMWPE. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined composite bearing inserts for knee joints, as taught by Burstein *et al.* in the invention of Lidgren *et al.*, and would have been motivated to do so since Burstein *et al.* suggests that such composite bearing inserts for knee joints minimizes or eliminates the production of wear debris resulting from relative motion at the interface between endoskeleton and composite knee joint assembly (1:6-12).

Claims 155-159 and 166-168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US 6,448,315).

Regarding claims 155-159, 166-167: Lidgren *et al.* teaches ultra-high molecular weight polyethylene (UHMWPE powder) particles doped with an antioxidant {doped with vitamin E (α-tocopherol)} (abstract, 1:5-11; 3:63-4:3; 4:15-32; 4:45-50; 8:33-34; ex. 1-2) via mixing UHMWPE with Vitamin E and then diffusion doping {supercritical CO_2} (4:46-5:11); with subsequent exposure to γ-irradiation at a dose above 2 Mrad, followed by annealing at a temperature of above 80 °C {remelting} (6:8-18; 6:45-68; 7:1-15); wherein irradiating/annealing can be carried out at any stage in the manufacturing process, from powder to implant (6:16-18). Lidgren *et al.* teaches medical implants (6:1-7). Lidgren *et al.* teaches

compression molding the UHMWPE particles doped with vitamin E into blocks {consolidation}, and machining rods from the blocks {deforming}, with subsequent exposure to γ-irradiation (7:1-15). Lidgren *et al.* teaches γ-irradiation at a dose above 2 Mrad, as well as between 0–200 kGy, with specific doses of 80, 100 and 200 kGy at room temperature (6:8-18; 6:45-68; 7:1-15; Table 1).

Lidgren *et al.* does not teach γ-irradiating at a temperature above room temperature {RT}. However, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) [See MPEP 2144.05]. Therefore, at the time of invention a person of ordinary skill in the art would have found it obvious to have irradiated at a temperature above room temperature as above room temperature is close enough to room temperature.

Regarding claim 168: Lidgren *et al.* teaches joint prostheses (6:1).

Claim 169 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US 6,448,315), as applied to claim 167 above, in further view of Saum *et al.* (US 2002/0107300), when taken with Wolf *et al. J. Mat. Sci.: Mat in Med*, **2006**, *17*, 1341-1347.

Regarding claim 169: Lidgren *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 167]; wherein the implant is packaged and sterilized (6:1-8).

Lidgren *et al.* does not teach sterilization via ionizing gas radiation or gas sterilization [instant claim 169]. However, Saum *et al.* teaches a method of making crystalline crosslinked ultrahigh molecular weight polyethylene (UHMWPE) implants (abstract, ¶ 9, 13); wherein the implant is packaged and gas plasma sterilized (¶ 20). Lidgren *et al.* and Saum *et al.* are

analogous art because they are concerned with a similar technical difficulty, namely the preparation of irradiated UHMWPE for medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined gas plasma sterilization of the packaged implant, as taught by Saum *et al.* in the invention of Lidgren *et al.*, and would have been motivated to do so since Saum *et al.* suggests that gas plasma sterilization of packaged implants is known in the art (¶ 20).

Wolf *et al.* provides evidence that α-tocopherol fails to show any in-vitro cytotoxic or genotoxic activity when used in-vitro in UHMWPE implants (abstract).

Claims 160-165 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US 6,448,315), as applied to claim 155 above, and further in view of Mckellop *et al.* (WO 99/52474).

Regarding claims 160-165: Lidgren *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 155].

Lidgren *et al.* does not teach irradiating at a temperature of about: 90 °C [instant claim 160]; 100 °C [instant claim 161]; 110 °C [instant claim 162]; 120 °C [instant claim 163]; 130 °C [instant claim 164]; 135 °C [instant claim 165] However, Mckellop *et al.* teaches UHMPE for medical implants (pg. 1, ln. 25-30; pg. 3, ln. 10-21) irradiated at a temperature below the melt [instant claims 160-165] (pg. 15, ln. 15-18) {note $T_{m\,peak}$ of UHMWPE ~135 °C}. Lidgren *et al.* and Mckellop *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of irradiated UHMWPE for medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined

irradiated at a temperature below the melt (pg. 15, ln. 15-18), as taught by Mckellop *et al.* in the invention of Lidgren *et al.*, and would have been motivated to do so since Mckellop *et al.* suggests that irradiated at a temperature below the melt provides surface crosslinking (pg. 15, ln. 15-18).

Claims 170-174, 181-185 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US 6,448,315), as applied to claim 125 above, in further view of Burstein *et al.* (US 6,620,198).

Regarding claims 170-174, 181-185: Lidgren *et al.* teaches ultra-high molecular weight polyethylene (UHMWPE powder) particles doped with an antioxidant {doped with vitamin E (α-tocopherol)} (abstract, 1:5-11; 3:63-4:3; 4:15-32; 4:45-50; 8:33-34; ex. 1-2) via mixing UHMWPE with Vitamin E and then diffusion doping {supercritical CO_2} (4:46-5:11); with subsequent exposure to γ-irradiation at a dose above 2 Mrad, followed by annealing at a temperature of above 80 °C {remelting} (6:8-18; 6:45-68; 7:1-15); wherein irradiating/annealing can be carried out at any stage in the manufacturing process, from powder to implant (6:16-18). Lidgren *et al.* teaches medical implants (6:1-7). Lidgren *et al.* teaches compression molding the UHMWPE particles doped with vitamin E into blocks {consolidation}, and machining rods from the blocks {deforming}, with subsequent exposure to γ-irradiation (7:1-15). Lidgren *et al.* teaches γ-irradiation at a dose above 2 Mrad, as well as between 0–200 kGy, with specific doses of 80, 100 and 200 kGy at room temperature (6:8-18; 6:45-68; 7:1-15; Table 1).

Lidgren *et al.* does not teach γ-irradiating at a temperature above room temperature {RT}. However, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) [See MPEP 2144.05]. Therefore, at the time of invention a person of ordinary skill in the art would have found it obvious to have irradiated at a temperature above room temperature as above room temperature is close enough to room temperature.

Lidgren *et al.* teaches implants, especially joint prostheses, are fabricated from the UHMWPE having excellent wear resistance via compression molding directly into implants or into blocks from which the implant is machined (6:1-18).

Lidgren *et al.* does not specifically teach forming an interface or an interlocked hybrid material. However, Burstein *et al.* teaches composite bearing inserts for knee joints (abstract), wherein the tibial component includes a metal tibial element and a composite bearing insert structure attached to the metal tibial element. The polymeric bearing is interlocked with the metal tibial element [instant claims 170-171, 182-184] (1:65-2:7; 2:16-25), wherein the polymeric material includes UHMWPE (5:1-7), and the polymer insert and tibial tray are interlocked through dovetails, or screw arrangement {porous (metallic) material} [instant claim 185] (2:10-25). Lidgren *et al.* and Burstein *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of medical implants containing UHMWPE. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined composite bearing inserts for knee joints, as taught by Burstein *et al.* in the invention of Lidgren *et al.*, and would have been motivated to do so since Burstein *et al.*

suggests that such composite bearing inserts for knee joints minimizes or eliminates the production of wear debris resulting from relative motion at the interface between endoskeleton and composite knee joint assembly (1:6-12).

Claims 175-180 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US 6,448,315) in view of Burstein *et al.* (US 6,620,198), as applied to claim 170 above, and further in view of Mckellop *et al.* (WO 99/52474).

Regarding claims 175-180: Lidgren *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 170].

Lidgren *et al.* does not teach irradiating at a temperature of about: 90 °C [instant claim 175]; 100 °C [instant claim 176]; 110 °C [instant claim 177]; 120 °C [instant claim 178]; 130 °C [instant claim 179]; 135 °C [instant claim 180] However, Mckellop *et al.* teaches UHMPE for medical implants (pg. 1, ln. 25-30; pg. 3, ln. 10-21) irradiated at a temperature below the melt [instant claims 160-165] (pg. 15, ln. 15-18) {note $T_{m\,peak}$ of UHMWPE ~135 °C}. Lidgren *et al.* and Mckellop *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of irradiated UHMWPE for medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined irradiated at a temperature below the melt (pg. 15, ln. 15-18), as taught by Mckellop *et al.* in the invention of Lidgren *et al.*, and would have been motivated to do so since Mckellop *et al.* suggests that irradiated at a temperature below the melt provides surface crosslinking (pg. 15, ln. 15-18).

Claim 186 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US 6,448,315), in view of Burstein *et al.* (US 6,620,198), as applied to claim 182 above, in further view of Saum *et al.* (US 2002/0107300), when taken with Wolf *et al. J. Mat. Sci.: Mat in Med*, **2006**, *17*, 1341-1347.

Regarding claim 186: Lidgren *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 182]; wherein the implant is packaged and sterilized (6:1-8).

Lidgren *et al.* does not teach sterilization via ionizing gas radiation or gas sterilization [instant claim 186]. However, Saum *et al.* teaches a method of making crystalline crosslinked ultrahigh molecular weight polyethylene (UHMWPE) implants (abstract, ¶ 9, 13); wherein the implant is packaged and gas plasma sterilized (¶ 20). Lidgren *et al.* and Saum *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of irradiated UHMWPE for medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined gas plasma sterilization of the packaged implant, as taught by Saum *et al.* in the invention of Lidgren *et al.*, and would have been motivated to do so since Saum *et al.* suggests that gas plasma sterilization of packaged implants is known in the art (¶ 20).

Wolf *et al.* provides evidence that α-tocopherol fails to show any in-vitro cytotoxic or genotoxic activity when used in-vitro in UHMWPE implants (abstract).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 125-127, 132-133 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 72, 74, 63, 80-81, 86 of copending Application No. 11/465,509. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed method steps substantially overlap in scope. '509 annealing below T_m, whereas the instant application deforms the blend below T_m and annealing below T_m. It would have been obvious to one having skill in the art to perform steps d-e below the melt in order to reduce orientation and/or reduce thermal stress.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 5/24/10 have been fully considered but they are not persuasive. The rejection of claims 125-186 based upon Lidgren *et al.* (US 6,448,315) is maintained for reason of record and the following response.

Lidgren *et al.* (US 6,448,315) was relied on for disclosing UHMPE particles doped with an antioxidant {doped with vitamin E (α-tocopherol}) (abstract, 1:5-11; 3:63-4:3; 4:15-32; 4:45-50; 8:33-34)} via diffusion doping {supercritical CO_2} (4:46-5:11); with subsequent exposure to γ-irradiation at a dose above 2Mrad, followed by annealing remelting (6:8-18; 6:45-68; 7:1-15); wherein irradiating/annealing can be carried out at any stage in the manufacturing process, from powder to implant (6:16-18). Lidgren *et al.* teaches medical implants (6:1-7).

While Lidgren *et al.* (US '315) employs a supercritical CO_2 diffusion doping process, the instant claims fail to exclude such a process, therefore any process can be employed which introduces the additive into the polymeric material. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., >*Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) [see MPEP 2111.03]. As Lidgren *et al.* (US '315) discloses compression molding the UHMWPE particles doped with vitamin E into blocks {consolidation}, and machining rods from the blocks {deforming}, with subsequent exposure to γ-irradiation (7:1-15), the examiner takes the position that that supercritical CO_2 diffusion doping process affording ultra-high molecular weight polyethylene (UHMWPE powder) particles doped with an antioxidant {doped with vitamin E (α-tocopherol)} reads on applicant's step of mixing a polymeric material with one or additives to form a blend.

Furthermore, the instant specification recites that 'blending" generally refers to mixing of a polyolefin in its pre-consolidated form with an additive; and in the case where an additive is an antioxidant, for example vitamin E, or α-tocopherol, then the blended polymeric material is also antioxidant-doped (pg. 57, ln. 24-pg. 58, ln. 6). The specification further states that "doping"

refers to a process of contacting a polymeric material with an antioxidant, for example, doping UHMWPE with an antioxidant under supercritical conditions (pg. 58, ln. 22-pg. 59, ln. 5); i.e. the supercritical CO_2 diffusion doping process of Lidgren *et al.* (US '315) [UHMWPE powder particles doped with an antioxidant {doped with vitamin E (α-tocopherol)}] appears to be synonymous with an antioxidant-doped material, aka a blended polymeric material which is antioxidant-doped (pg. 57, ln. 24-pg. 58, ln. 6).

While Lidgren *et al.* does not teach the process steps in the same order of instant claim 125, a prima facie case of obviousness exists where changes in the sequence of adding ingredients derived from the prior art process steps. *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results*);* *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.) [See MPEP 2144.04].

While Saum *et al.* (US 2002/0107300) discloses the UHMWPE employed does not contain stabilizers, antioxidants, or other chemical additives which may have potential adverse effects in medical applications (¶ 12), one having skill in the art would employ the supercritical doping process of UHMWPE with vitamin E (α-tocopherol} as disclosed in Lidgren *et al.* (US '315) {see above} since vitamin E (α-tocopherol) fails to show any in-vitro cytotoxic or genotoxic activity (i.e. α-tocopherol does not have any adverse effects when used in-vitro in UHMWPE implant, therefor one reading the disclosure of Saum *et al.* (US '300) would include non-toxic antioxidants (α-tocopherol)}, as evidenced by Wolf *et al. J. Mat. Sci.: Mat in Med*, **2006**, *17*, 1341-1347 {see abstract, and ref. 11}. In response to applicant's argument that there is

no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Lidgren *et al.* suggests that UHMWPE diffusion doped with antioxidants provides reduced oxidation during sterilization and post sterilization and thereby decrease the wear of the implant in the body (4:15-32; 6:1-18), and Wolf *et al.* provides evidence that α-tocopherol fails to show any in-vitro cytotoxic or genotoxic activity when used in-vitro in UHMWPE implants (abstract).

Mckellop *et al.* (WO 99/52474) was relied on for disclosing UHMPE for medical implants (pg. 1, ln. 25-30; pg. 3, ln. 10-21) irradiated at a temperature below the melt (pg. 15, ln. 15-18) {note $T_{m\,peak}$ of UHMWPE ~135 °C}, which provides surface crosslinking (pg. 15, ln. 15-18). Mckellop *et al.* discloses compression molding UHMWPE and UHMWPE/peroxide blend at 2000 psi (~ 14 MPA}, heating to a temperature of 170 °C for 2 h, then slow cooled to RT at 2000 psi (pg. 36, ln. 31-pg. 37, ln. 21; pg. 40, ln. 5-36). Mckellop *et al.* teaches stabilization against long term oxidation via annealing the implant (pg. 4, ln. 23-36; pg. 37, ln. 10-14); i.e. the annealing step in example 6 would provide long term oxidation, as Mckellop *et al.* teaches stabilization against long term oxidation via annealing the implant (pg. 4, ln. 23-36) [see also *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) [see MPEP

2112.01]. Evidence {data} would be need to be provided showing that the process of Mckellop *et al.* does not provide an oxidation resistant cross-linked polymeric material.

Burstein *et al.* (US 6,620,198) was relied on for composite bearing inserts for knee joints (abstract), wherein the tibial component includes a metal tibial element and a composite bearing insert structure attached to the metal tibial element. The polymeric bearing is interlocked with the metal tibial element (1:65-2:7; 2:16-25), wherein the polymeric material includes UHMWPE (5:1-7), and the polymer insert and tibial tray are interlocked through dovetails, or screw arrangement {porous (metallic) material} (2:10-25). Burstein *et al.* suggests that such composite bearing inserts for knee joints minimizes or eliminates the production of wear debris resulting from relative motion at the interface between endoskeleton and composite knee joint assembly (1:6-12).

Muratoglu *et al.* (US 2003/0149125) was relied on for disclosing UHMPE for medical implants (¶ 1, 9), wherein the irradiated UHMWPE undergoes uniaxial deformation (¶ 27), specifically uniaxial compression deformation at about 133 °C with a compression ratio of about 2, or about 4.5 (¶ 90, 97, 112, 116); mechanical deformation at an elevated temperature reduces the concentration of residual free radicals (¶ 48, 99, 119-120).

The provisional nonstatutory obviousness-type double patenting of claims 125-127, 132-133 over claims 72, 74, 63, 80-81, 86 of copending Application No. 11/465,509 is maintained [see above].

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL PEPITONE whose telephone number is (571)270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Pepitone/
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